



# COLD CHAIN VALIDATION



Bringing Sharpness to the Quality of Life Science

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Cold chain in Food Sector

Temperature monitoring

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Thank You

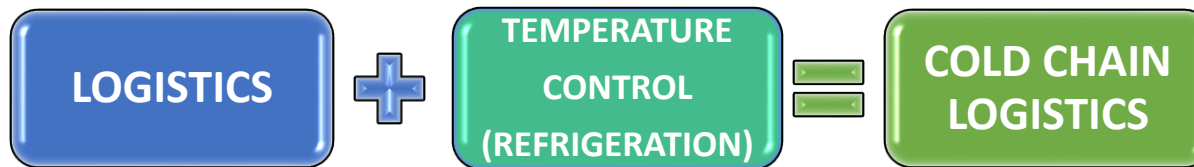
Content

Bringing Sharpness to the Quality of Life Science

# What is Cold Chain

Cold chains are universally used in the food, pharmaceutical and some chemical shipments. The **cold chain** is a logistical system which manages temperature, often between 2° to 8° Celsius. It is a series of distribution activities which continuously maintain this temperature in order to protect the temperature-sensitive cargo from manufacture to the point of consumption. Unique to fresh produce cargoes, the cold chain requires to additionally maintain product specific environment parameters—which include air quality levels (carbon dioxide, oxygen, humidity and others) which makes this the most complicated cold chain to operate.

It is important for every cold storage to have a refrigerant, a valve, a vapour barrier and insulation during the cargo shipping, leakages may occur from the containers and when this happens, the temperature may increase which can lead to spoilage as well. In order to avoid such kind of problems, the containers have to be filled with insulators.



# Major Sectors:

## Food and Beverages, Bio-Pharmaceutical

- Immunization well-known and effective methods of preventing childhood diseases.
- India has one of the largest UIP (**Universal Immunization Programme**) in the world.
- Under UIP, all the children in the entire country are protected against the 6 deadly Vaccine Preventable Diseases (VPD)
- Services provided district hospitals, community health centers (CHC), primary health centers (PHC) and sub-centers.
- Important elements for improving the immunization is cold chain and vaccine logistics management which is backbone of immunization programme.
- It is a universal fact that all vaccines are sensitive to heat & light and some are sensitive to freezing
- A vaccine must have two characteristics, one is **safety** and other is **potency**
- vaccines loose their potency if they are not stored or transported at an appropriate temperature and condition



Fruits & Vegetables

Meat

Fish & Seafood

Dairy Products

Beverages



Pharmaceutical

Biotech

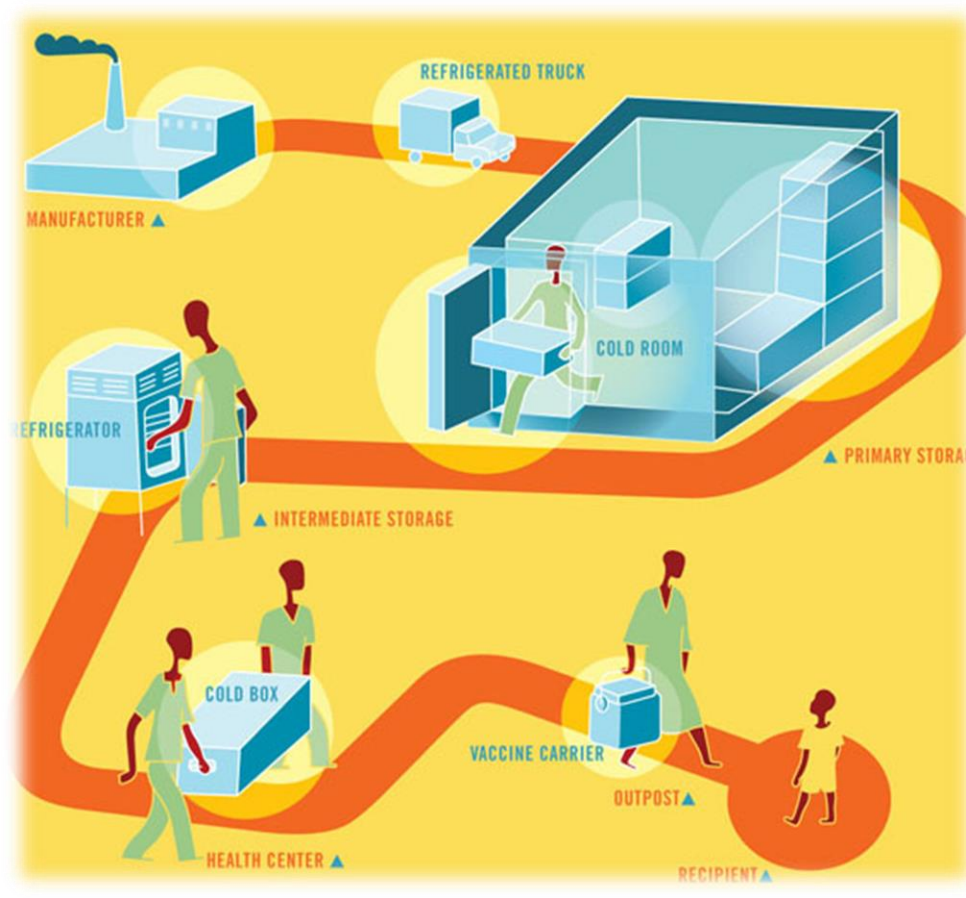
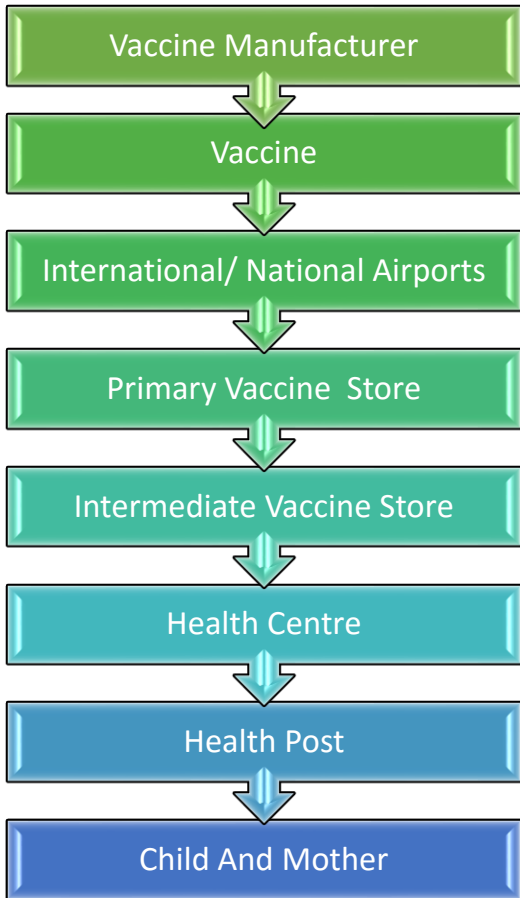
Vaccines

Blood Products

Clinical Trials



# Cold chain in Pharmaceutical Sector



Pharmaceutical



Biotech



Vaccines



Blood Products



Clinical Trials

# Cold Chain in Food Sector



Fruits & Vegetables

Meat



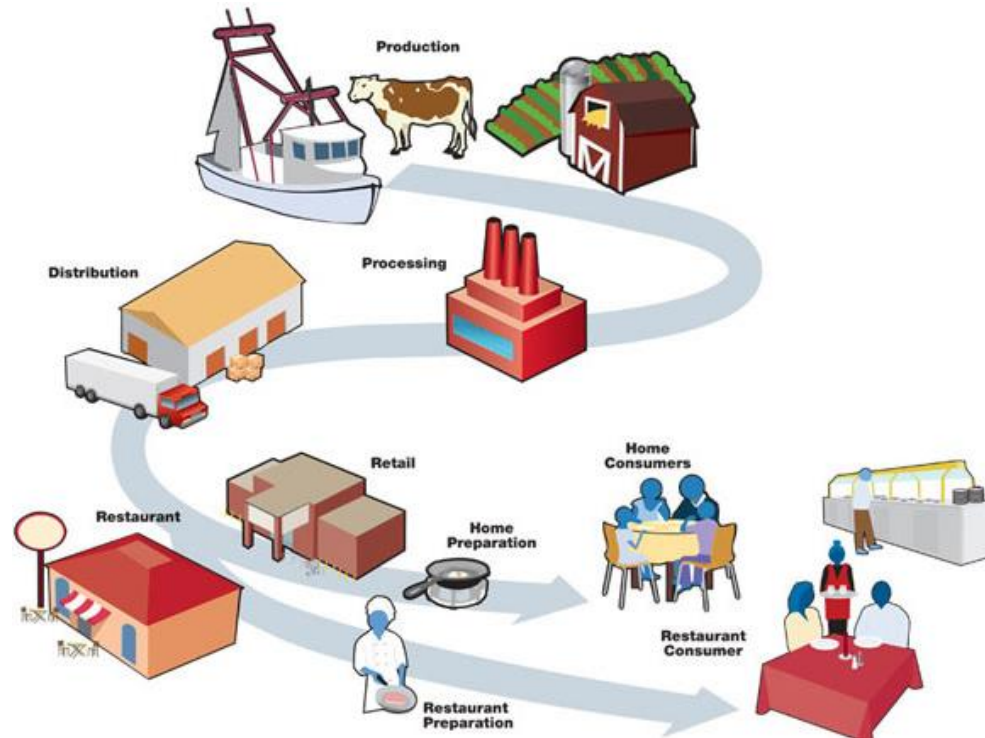
Fish & Seafood



Dairy Products



Beverages



Farm (Point of Harvest)

Pre-cooling

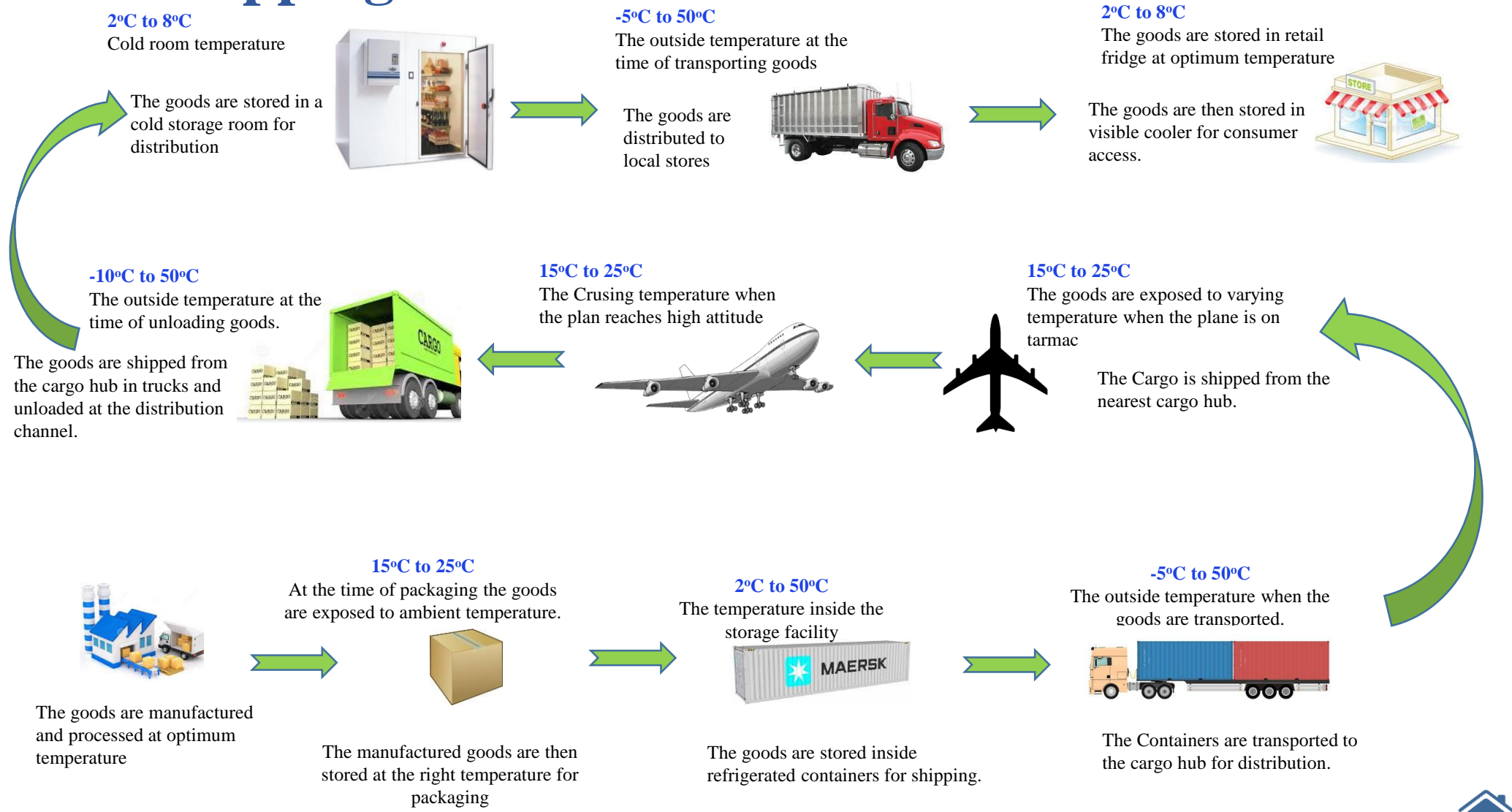
Cold Storage

Packaging & Processing

Storage/ Distribution

Retail(Point of Sale)

# Temperature monitoring is important when shipping cold chain assets



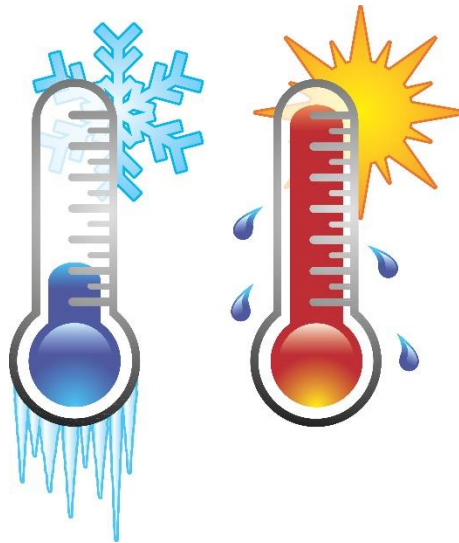
# Some Facts .....

- All Vaccines lose their potency due to either exposure to excessive heat (More than +8°C) or excessive cold or light permanently which can not be regained and the physical appearance of the vaccine may remain unchanged even after it is damaged.
- There is a **GROWING** international demand for increasingly **EXPENSIVE** pharma and biopharma products.
- Life-saving products like vaccines (\$35 billion market by 2015) are often **temperature-sensitive**, requiring temperature-controlled shipping from manufacturer to end user.
- With growing volume and cost-per-product, by 2014, \$16 billion worth of biological and vaccine shipments will require temperature-controlled rooms during transit.
- The World Health Organization (WHO) reported that as recently as 2005, nearly half of all vaccines were **RUINED** in transit due to poor cold chain services.
- In a billion-dollar market, wasted product spells dwindling returns, to say nothing of the impact on world health.
- Effective cold chain shipping is therefore critical, particularly as pharma and biopharma cold chain shipments in established and emerging markets grow dramatically in the coming years.

## Freeze sensitive vaccines

- ☞ Most sensitive
- HepB
  - DPT
  - DT
  - TT

Least sensitive:  
The effect of freezing is not cumulative, once frozen it is of no use



## Heat sensitive vaccines

- ☞ Most sensitive
- BCG (after reconstitution)
  - OPV
  - Measles (both before and after reconstitution)
  - DPT
  - BCG (after reconstitution)
  - DT
  - TT
  - HepB

Least sensitive:  
The damage of heat is cumulative and cannot be reversed by re-freezing the vaccine.





# Benefits & Demands

The cold chain is a well-known method for reducing losses and wastages.

The primary segments of an integrated cold chain, which include;

- 1) Packing and cooling fresh food products,
- 2) Food processing (i.e. freezing of certain processed foods,
- 3) Cold storage (short or long term warehousing of chilled or frozen foods),
- 4) Distribution (cold transport and temporary warehousing under temperature controlled conditions),
- 5) Marketing (refrigerated or freezer storage and displays at wholesale markets, retail markets and foodservice operations) can be simple or complex, low tech or high tech.

Cold chain logistics is the planning and management of the interactions and transitions between these five segments, in order to keep product at their optimum temperature for maintenance of quality, food safety and prevention of waste and economic losses. Speed is often the key to success when handling and marketing perishable product.

## Benefits:-

- It creates consistent results that the company can rely on.
- It helps earn trust of product to end-users.
- It opens opportunities for powerful business marketing.
- It can boost employees sense of professionalism.
- It can create bigger money-savings.

## Demands:-

- India is among the top five emerging pharma markets and has grown at an estimated compound annual growth rate (CAGR) of 13 Percent during the period FY 2009-2013. The Indian pharmaceutical market is poised to grow to 3300 billion by 2020 from the 2009 levels of 756 billion.
- The ever growing pharmaceutical industry is acutely temperature and time sensitive. Cold supply chain acts like a backbone for pharma industry. It is a big responsibility to have a regulatory supervision and to maintain the efficacy of the drug throughout the supply chain in order to main the quality of drugs and comply with statutory requirements.

# Challenges & Risks

## Challenges:-

- Lack of Road Infrastructure
- Continuity of the cold supply chain
- Uneven distribution of cold chains
- High capital investment  
₹.80-90/- sq.ft.(\$1.6-2.0) against ₹.30/- sq.ft.(\$ 0.6) in west
- Power supply  
-17-18% power deficit  
-30% of total expenses against 10% in west
- Management of different temperatures
- Awareness & Mindsets
- Error Irreversibility  
Highly temperature sensitive cargo

## Risks:-

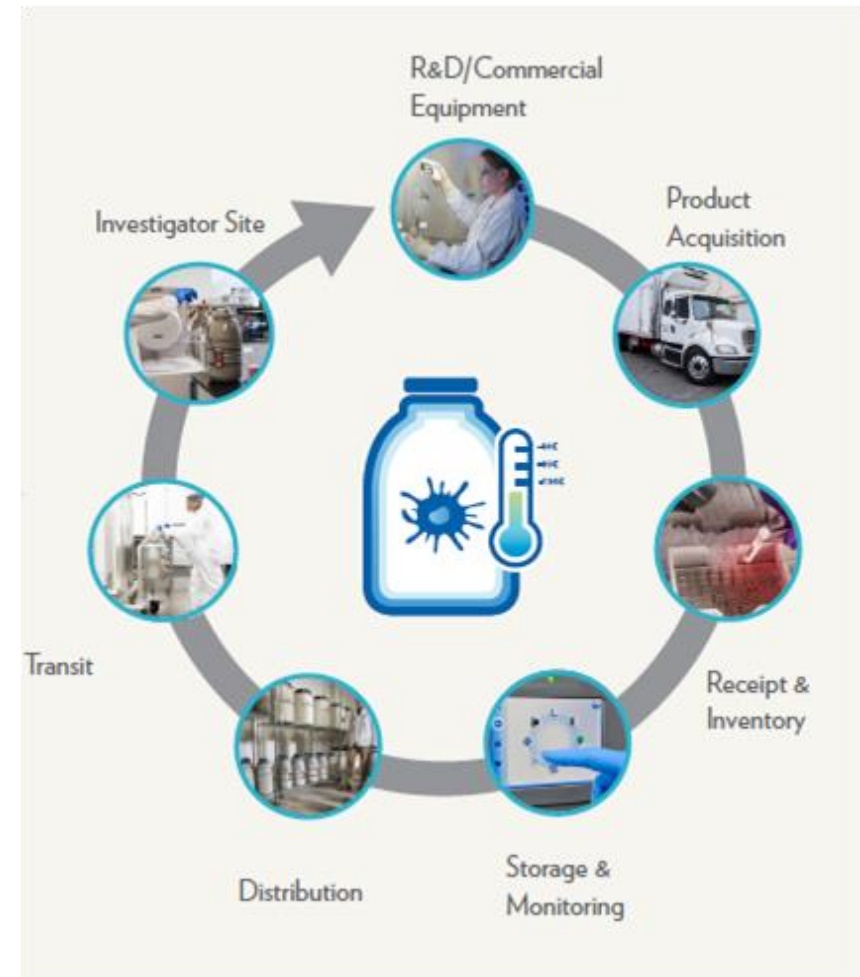


# Maintaining Consistent Quality

When it comes to proper storage and distribution, the right packaging is required not only to completely seal in temperature-sensitive products and prevent interaction with potentially contaminating elements but also to maintain the ideal temperature that will preserve the original quality of the products whilst in transit. Typically, temperature controlled packaging consists of several items including an outer shipper, inner polyurethane foam insulated box, gel bricks and gel packs and foam sheets, which together create a temperature controlled system validated for specific temperatures and time frames.

For cold chain packaging which is used for drugs and biological elements, insulating materials are polyurethane and Styrofoam with polyurethane being deemed as the better option because it can maintain original temperatures for up to 4 days. Meanwhile, for frozen goods, frozen gel bricks are commonly used to keep the good in the right temperature throughout transport. As for chilled products, chilled gel packs that are commonly included in the coolers. All these make sure that the content arrives at its destination in good condition despite exterior climate. Among the items that require temperature controlled packaging are the following:

1. Vaccines and serums;
2. Medicines that are still undergoing research and clinical trials, hence, maintaining their original composition is critical to the successful outcome of the study;
3. Blood samples for transfusion or study. Maintaining ideal cool temperature for them is crucial because studies show that plasma zinc concentrations increase 6.3 per cent at 1 hour and 40.7 per cent at 24 hours, whereas serum zinc concentrations increased at 0.9 per cent at 1 hour and 12.5 per cent at 24 hours in uncontrolled temperatures;
4. Organs for transplant because they are deprived of oxygen blood supply the moment they are removed from the donor but placing them in the right temperature controlled container or packaging automatically restricts the amount of damage that can occur;
5. Biological specimens and certain food products that are frozen, raw and not endemic to the area;



# Why Autocal

It's a wake-up call to all businesses involved in the cold chain process, not only in the US but all over the world. Indian companies and regulatory bodies regarded the news as motivation to further persevere in ensuring that the integrity of our cold chain remains intact. Certainly, related agencies made sure that cold chain validation was a priority in their audit list. The efficacy of many temperature sensitive drugs, medicines and vaccines can be a matter of life or death if the drugs prove to be ineffective due to them having not been stored or transported under temperature controlled conditions. Besides the possible tragedies that could stem from products being compromised in storage or in distribution, there are also the other crucial matters of reputation and liability.

Companies can consult literature on the appropriate legislations, but it would be more prudent to get assistance from industry experts. Cold chain consultants like [Autocal](#) have the knowledge, equipment, and experience necessary to develop, test, and implement cold chain systems for pharmaceutical and biotech companies. They have the appropriate testing chambers and tools, data-recording equipment, and other related equipment, all calibrated to pass international standards.

Cold chain specialists are aware that temperature mapping is not the be-all and end-all of the process as it is an indication of the temperature within a warehouse, fridge or freezer at a particular point in time but it does help to highlight and fix issues. Cold Chain Consultants can help clients in all areas of cold chain management from meeting regulation requirements and implementing quality management systems to validating and qualifying equipment and facilities as well as designing and validating cold chain mechanisms. They also advise regarding logistic options and best distribution practices.

If you need proof of your compliance with official standards, [Autocal](#) can supply you with all the necessary documentation pertaining to protocol, validation or qualification reports, engineering reports, as well as packing details vis-a-vis photos and videos.

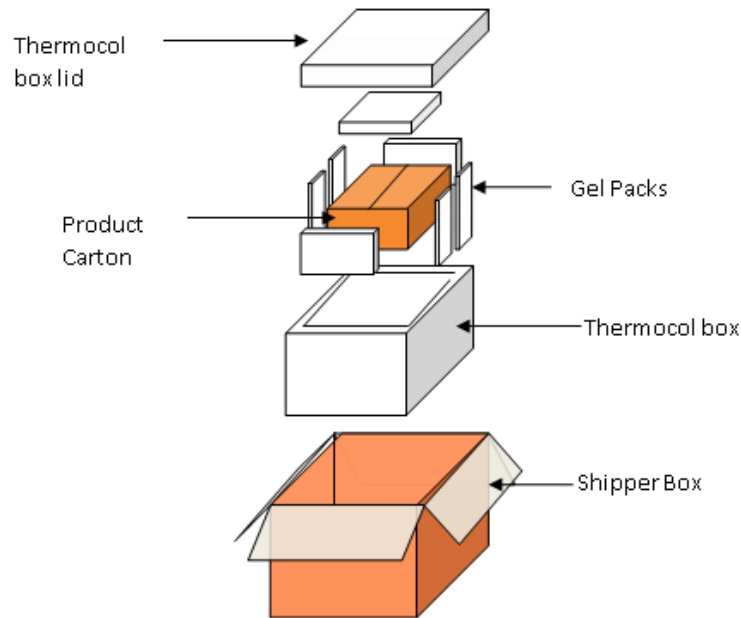
The protection of regulatory controlled drugs from exposure to unsuitable climatic conditions and the strict adherence to cold chain compliance standards are duly addressed in legislation in almost all countries. To protect your business, your associates, and your consumers, make sure you undergo validation.





# In transit Solution

## Equipment for vaccine transportation – Cold Box



Every medicine or life saving drug has a different packaging need to keeping them in a stable environment in transit & it's a major challenge faced by many pharmaceuticals companies and testing laboratories. The extreme temperature variances in our country make it a necessity to have specialized packaging solutions for these drugs. Autocal provides this isolated container with a tight fitting lid & cooling packs/ icepacks for maintaining the temperature inside depending on the customer requirements from pickup to delivery. Temperature control during shipping is critical to prevent any damage to the biological specimens or pharmaceutical materials, our solutions help in resolving this issue.

This solution caters for three inner temperature ranges:

- Cold ( +2C to +8C )
- Controlled Ambient ( +15C to +25C )
- Freezing ( -25C to -15C ) / ( -60C to -80C )

When required, a data logger can be added to record temperature during shipping. Customers can check the inner temperature surrounding the payload, at any time during transportation according to their needs.

Insulated box with a tight fitting insulated lid suitable for

- Collection & Transportation of small and Large quantities of vaccine during working days to avoid frequent opening of refrigerators;
- Storage of small quantities for emergencies;
- Storage during maintenance periods (cleaning);
- Emergency storage (breakdown of cold chain, power failures).

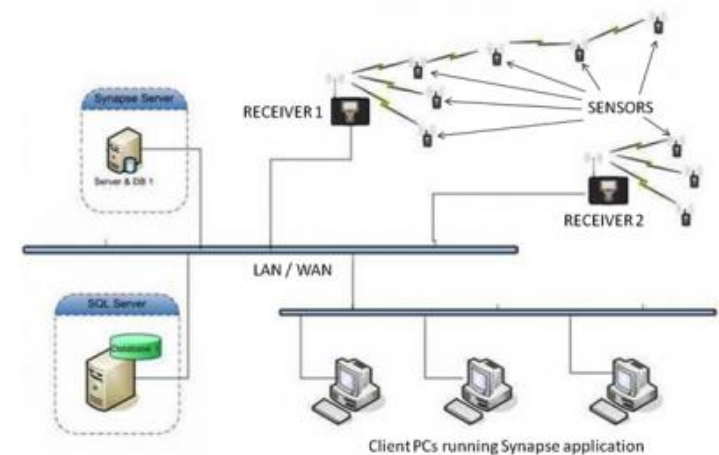
# Temperature Monitoring Device

## Testo 174 T set - Mini Temperature

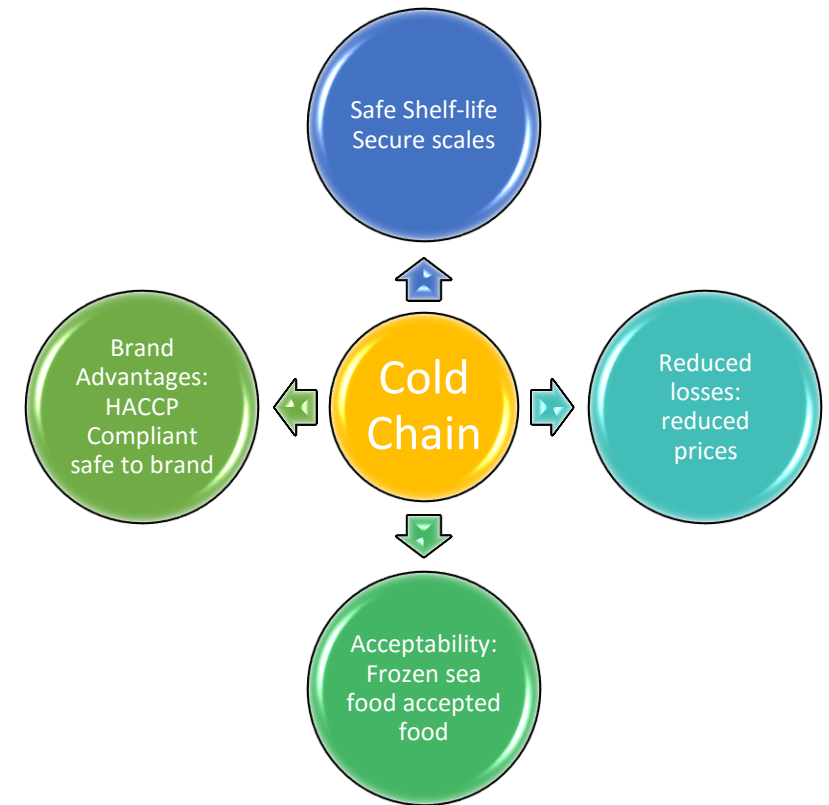
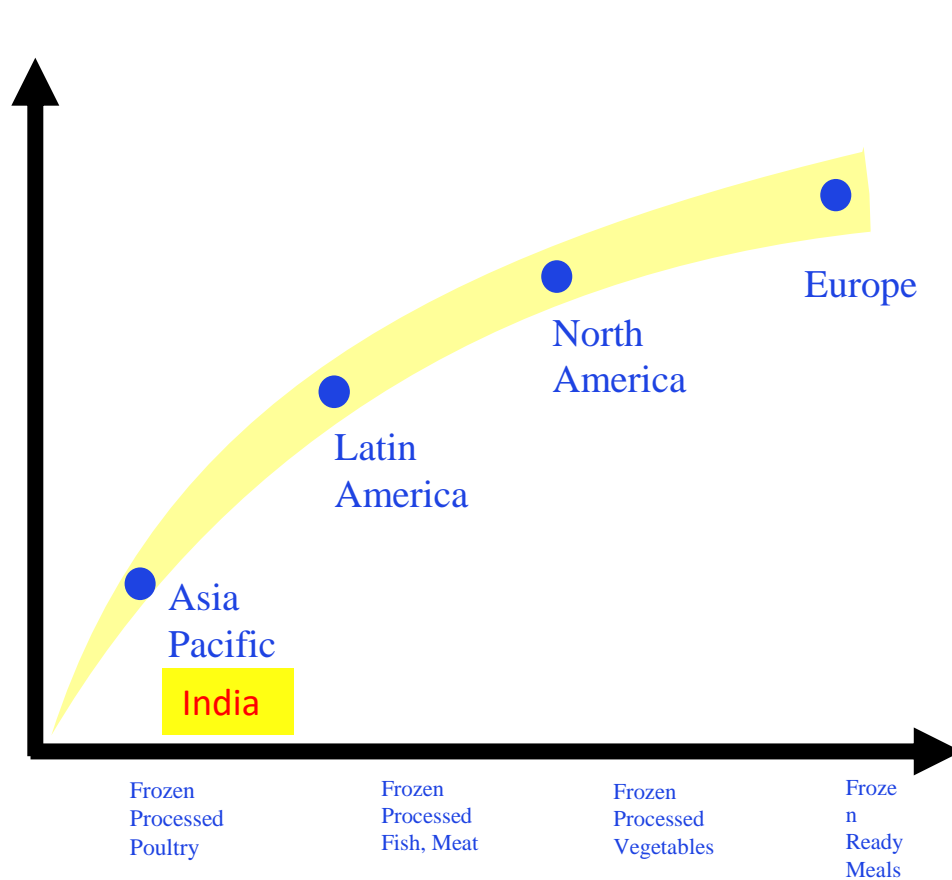
Temperature Monitoring is a critical part of good storage and handling practice. **AUTOCAL** recommends using only a calibrated digital data logger with a current and valid certificate of calibration testing (also known as a Report of Calibration). This certificate informs the user of a temperature monitoring device's level of accuracy compared to a recognized standard. Calibrated temperature monitoring devices are required for providers who receive VFC vaccines or other vaccines purchased with public funds.

Data Logger is used for Monitoring and documentation of the temperature in cold rooms & storage. It is widely used to monitor temperature in order to protect sensitive goods in the Food Manufacturing, Food Distribution, Super markets, Restaurants, Kitchens, Hospitals, Pharmacies, Medical & Pharmaceutical laboratories. Many foods and drugs have to be stored within a specific cold temperature range. This can be done in individual cooled store rooms, but also in specialised cold stores or cold warehouses with high-rack facilities. The temperature must be continuously documented in all these cold storage facilities, because strict rules apply to quality management in both the food and drugs industries. All temperature monitoring devices, through normal use, drift over time, which affects their accuracy. Because of this, temperature monitoring devices should undergo periodic calibration testing. Testing should be performed every 1 to 2 years from the last testing date or according to the manufacturer's suggested timeline. **AUTOCAL** recommends that testing meets standards defined in the Vaccine Storage and Handling Toolkit. If calibration testing indicates that your temperature monitoring device is no longer accurate, it should be replaced. Immunization programs are often excellent resources for information on temperature monitoring devices.

**AUTOCAL** recommends a back-up digital data logger for each vaccine storage unit. Temperature Monitoring Regular temperature monitoring is key to proper cold chain management. Store frozen vaccines (Varicella, MMRV, and Zoster) in a freezer between -58°F and +5°F (-50°C and -15°C). Store all other routinely recommended vaccines in a refrigerator between 35°F and 46°F (2°C and 8°C).



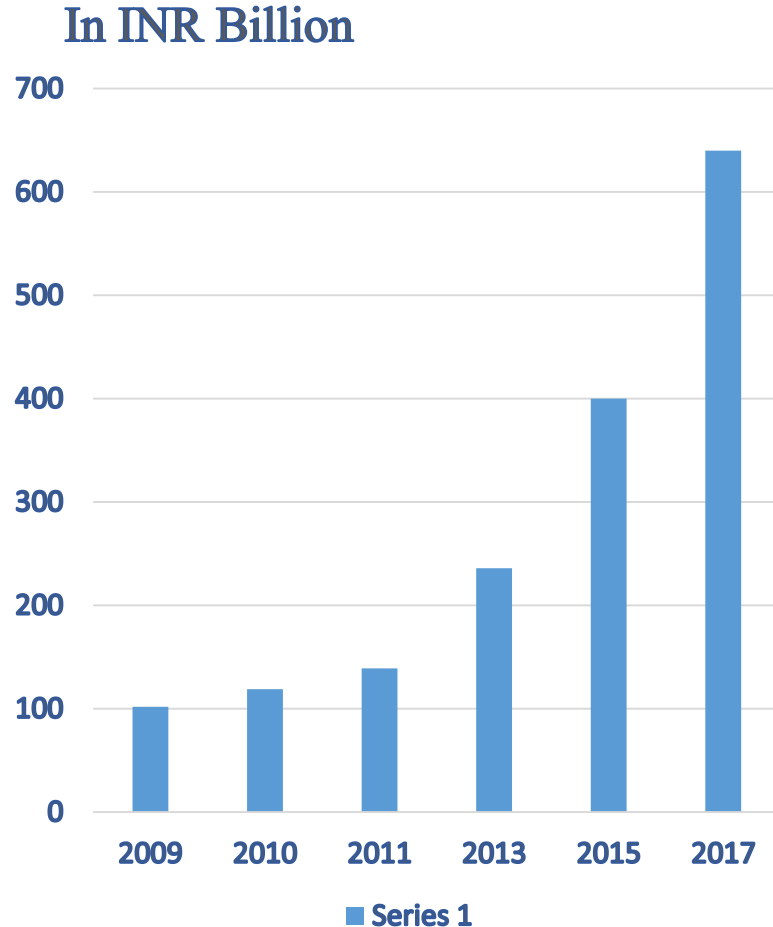
# Cold chain uses across the world



**India is still in the early stages of the development of a frozen food market.**

# Indian Cold chain Market Scenario

Projected Growth of India Cold Chain Market



- ❖ **11%** of Worlds Total Vegetables Production is accounted by India alone but India Share in global vegetable trade is only 1.7%.
- ❖ **127 Million Tones** of Milk was produced in 2011-12, but cold storage capacity is only available for 70,000-80,000 Tonnes of Milk.
- ❖ **20% -30%** of fish production is annually wasted in India.
- ❖ 25,000 unregistered slaughter houses are present in India, which generally lacks chilling facilities.



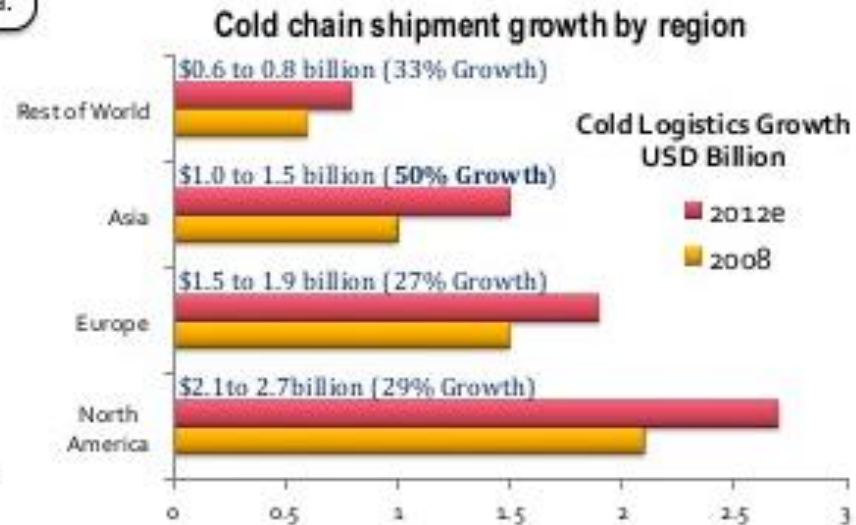
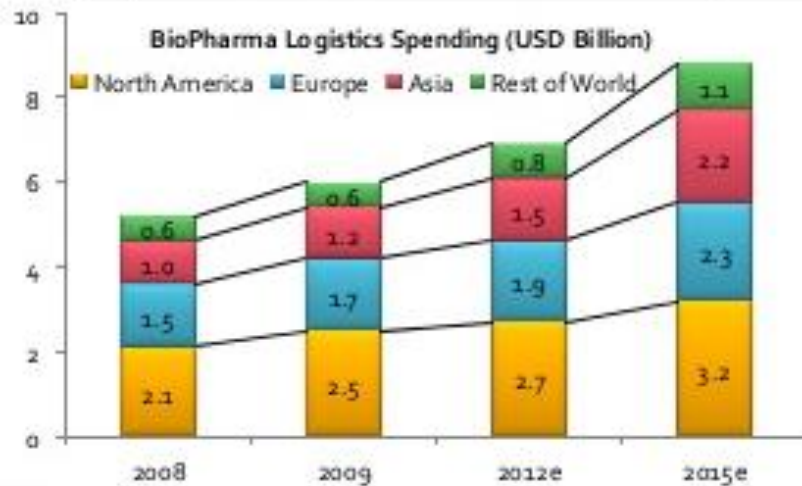
# Market Dynamics:

## Bio Pharma & Associated Logistics



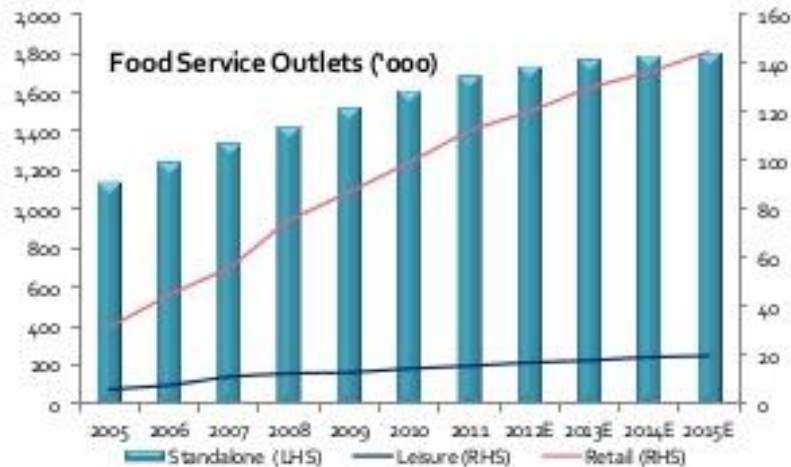
Higher-than-average growth in vaccines & specialty pharmaceuticals and heightened regulatory requirements continues to drive cold chain for pharma.

- **Global Cold chain logistics spend** from \$5.2 billion in 2008 to \$6.9 billion in 2012.
- Growth in Asia outstripped all regions.
- Asia & India continue to grow into a major hub for Bio-Pharma, cold chain demand from the sector continues to rise.



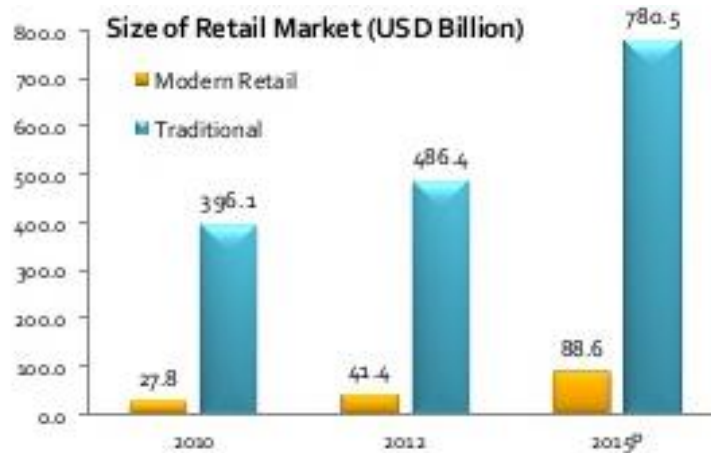
# Market Dynamics:

## Growth in Retail & Food Service



- India is 5th largest retail market worldwide.
- 1,968,000 Consumer Food outlets by 2015.

Organised Retail Market is growing despite FDI. This feeds demand for cold chain. Simultaneous growth in the food service sector accelerates need for the cold-chain.



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**Torah** Shipping & Logistics Pvt Ltd



**SGPharma**



**Microxpress®**



# THANK YOU

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